



EXPRESS MAIL NO. EV 452 774 090 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Ronald Pettis, *et al.*

Confirmation No.: 4733

Application No.: 09/893,746

Group Art Unit: 3763

Filed: June 29, 2001

Examiner: Michael J. Hayes

For: **A METHOD FOR ALTERING DRUG
PHARMACOKINETICS BASED ON
MEDICAL DELIVERY PLATFORM**

Attorney Docket No.: 11219-021-999
(500752-999020; P-4901P1)

Date: December 23, 2004

**SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. §1.56 AND §1.97**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to the references CM-DX listed on the attached revised form PTO 1449 entitled "List of References Cited by Applicant."

This application is a continuation-in-part of U.S. Serial No. 09/606,909 filed June 29, 2000. Pursuant to 37 C.F.R. § 1.98(d), copies of the listed references CM-DX have not been included herein as such copies are available in parent application U.S. Serial No. 09/606,909 filed June 29, 2000. Applicants will provide copies of references CM-DX upon request by the Examiner.

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use form PTO-1449, since this form identifies all of the references cited therein as "Prior Art." As an

alternative, Applicants submit herewith a "revised form PTO 1449" entitled "List of References Cited" instead of "List of Prior Art Cited".

Applicants respectfully request that the references be made of record in the file history of the application.

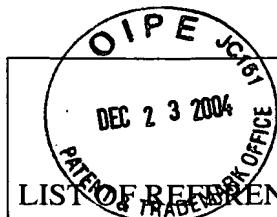
No fee is believed due. However, should the Patent and Trademark Office determine otherwise, please charge any required fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed for accounting purposes.

Respectfully submitted,

by: Jacqueline Penn
Reg. No. 43,492

Date: December 23, 2004

Laura A. Coruzzi 30,742
Laura A. Coruzzi (Reg. No.)
JONES DAY
222 East 41st Street
New York, New York 10017



LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO.
11219-021-999
(500752-999020,
P4901P1)

APPLICATION NO.
09/893,746

APPLICANT

Ronald Pettis, et al.

FILING DATE
June 29, 2001

GROUP
3763

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CM	4,886,499	12-1989	Cirelli, et al.			
	CN	5,279,552	01-1994	Magnet			
	CO	5,582,591	12-1996	Cheikh			
	CP	5,848,990	12-1998	Cirelli, et al.			
	CQ	6,056,716	05-2000	D'Antonio, et al.			
	CR	6,319,224	11-2001	Stout, et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	YES	NO
	CS	WO 94/23777	10/27/1994	PCT					
	CT	EP 0 429 842	08/28/1996	EP					
	CU	WO 97/21457	06/19/1997	PCT					
	CV	WO 00/09186	02/24/2000	PCT					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	CW	Agrawal, et al., Pharmacokinetics, Biodistribution, and Stability of Oligodeoxynucleotide Phosphorothioates in Mice, Proc. Natl. Acad. Sci. USA, Vol. 88, pp. 7595-7599, September 1991 Medical Sciences
	CX	Autret, et al., Comparison of Pharmacokinetics and tolerance of Calcitonine administered by Intradermal or Subcutaneous Route, Fundamental Clinical Pharmacology, Vol. 3, No. 2, pp 170-171, 1989
	CY	Benoni, et al., Distribution of Ceftazidime in Ascitic Fluid, Antimicrobial Agents and Chemotherapy, Vol. 25, No. 6, June 1984, pp. 760-763
	CZ	Bickers, et al., editors, Clinical Pharmacology of Skin Disease, pp. 57-90, Churchill Livingstone, Inc. 1984
	DA	Bocci, et al., The Lymphatic Route. IV. Pharmacokinetics of Human Recombinant Interferon a2 and Natural Interferon beta Administered Intradermally in Rabbits, International Journal of Pharmaceutics, 32, 1986, pp. 103-110 Elsevier Science Publishers B.V. (Biomedical Division)
	DB	Bronaugh RL, Stewart RF, Congdon ER. Methods for in Vitro Percutaneous Absorption Studies. II. Animal Models for Human Skin. Toxicol. Appl. Pharmacol. 1982 Mar 15;62(3):481-8.
	DC	Callen, Intralesional Corticosteroids, Journal of the American Academy of Dermatology, University of Louisville School of Medicine, pp. 149-151, 1981
	DE	Corbo M, Liu JC, Chien YW. Transdermal Controlled Delivery of Propranolol from a Multilaminate Adhesive Device. Pharm Res. 1989 Sep;6(9):753-8.
	DF	Cossum, et al., Disposition of the C-Labeled Phosphorothioate Oligonucleotide ISIS 2105 after Intravenous Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 1181-1190, Vol. 267, No. 3, 1993
	DG	Cossum, et al., Pharmacokinetics of C-Labeled Phosphorothioate Oligonucleotide, ISIS 2105 after Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 89-94, Vol. 269, No. 1, 1994
	DH	Crooke, et al., A Pharmacokinetic Evaluation of C-Labeled Afovirsen Sodium in Patients with Genital Warts, Clinical Pharmacology & Therapeutics, pp. 641-646, Vol. 56, No. 6, Part 1, December 1994
	DI	Firooz, et al., Benefits and Risks of Intralesional Corticosteroid Injection in the Treatment of Dermatological Diseases, pp. 363-370, Vol. 20, No. 5, Clinical and Experimental Dermatology, Blackwell Science Ltd, September 1995
	DJ	Goodarzi, et al., Organ Distribution and Stability of Phosphorothioated Oligodeoxyribonucleotides in Mice, Biopharmaceutics & Drug Disposition, pp. 221-227, Vol. 13, No. 3, John Wiley & Sons Ltd., April 1992



DK	Haynes, et al., Ultra-long-duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyflurane Microdroplets, <i>Anesthesiology</i> , Vol. 63, Vol. 5, pp. 490-499, Nov. 1985
DL	Jakobson, et al., Variations in the Blood Concentration of 1,1,2-Trichloroethane by Percutaneous Absorption and Other Routes of Administration in the Guinea Pig, Vol. 41, No. 5, pp. 497-506, <i>Acta Pharmacologica et Toxicologica</i> , November 1977
DM	Jarratt, et al., The Effects of Intradermal Steroids on the Pituitary-Adrenal Axis and the Skin, <i>The Journal of Investigative Dermatology</i> , Vol. 62, No. 4, pp. 463-466, 1974
DN	Kirkpatrick, et al., Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man, Vol. 67, No. 3A, <i>Anesthesiology</i> , September 1987
DO	Leroy, et al., Pharmacokinetics of Ceftazidime in Normal and Uremic Subjects, <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 25, No. 5, pp. 638-642, May 1984
DP	McAllister et al., Solid and Hollow Microneedles for Transdermal Protein Delivery. Proceed. Intl. Symp. Control. Rel. Bioact. Mater., 26 (Revised July 1999) Controlled Release Society, Inc. pp. 192-193
DQ	McGugan, et al., Adrenal Suppression from Intradermal Triamcinolone. <i>The Journal of Investigative Dermatology</i> , Vol. 40, pp. 271-272, Baltimore, MD., 1963
DR	Scott, et al., Toxicity of Interferon, Vol. 282, pp. 1345-1348, <i>British Medical Journal</i> , April 25, 1981
DS	Sebastien et al., Microfabricated Needles: A Novel Approach to Transdermal Drug Delivery, <i>Journal of Pharmaceutical Sciences</i> , Vol. 87, No. 8, August 1998, pp. 922-925
DT	Supersaxo, et al., Recombinant Human Interferon Alpha-2a: Delivery to Lymphoid Tissue by Selected Modes of Application, <i>Pharmaceutical Research</i> , Vol. 5, No. 8, pp. 472-476, August 1998
DU	Sutherest, Treatment of Pruritus Vulvae by Multiple Intradermal Injections of Alcohol. A Double-Blind Study, Vol. 86, pp. 371-373, <i>British Journal of Obstetrics and Gynecology</i> , May 1979
DV	Ward, et al., Puritus Vulvae: Treatment by Multiple Intradermal Alcohol Injections, Vol. 93, No. 2, pp. 201-204, <i>British Journal of Dermatology</i> , August 1975
DW	Wu, et al., Pharmacokinetics of Methoxyflurane after its Intra-Dermal Injection as Lecithin-Coated Microdroplets, Vol. 9, pp. 1-12, <i>Journal of Controlled Release</i> , July 1989
DX	Zaynoun, et al., The Effect of Intracutaneous Glucocorticoids on Plasma Cortisol Levels, Vol. 88, No. 2, pp. 151-156, <i>British Journal of Dermatology</i> , February 1973

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	